

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

MARK ONE WIPES, LLC
c/o Spangenberg Shibley & Liber LLP
1001 Lakeside Avenue East, Suite 1700
Cleveland, OH 44114

Plaintiff,

vs.

ALSTON & BIRD LLP
950 F Street, NW
Washington, DC 20004

and

KEVIN S. MINOLI, ESQ.
c/o Alston & Bird LLP
950 F Street, NW
Washington, DC 20004

and

ELISE N. PAEFFGEN, ESQ.
c/o Alston & Bird LLP
950 F Street, NW
Washington, DC 20004

and

SAMUEL D. JOCKEL, ESQ.
c/o Alston & Bird LLP
950 F Street, NW
Washington, DC 20004

and

BRENDAN CARROLL, ESQ.
c/o Alston & Bird LLP
950 F Street, NW
Washington, DC 20004

and

) CASE NO. 3:22-cv-00258

) JUDGE

) **PLAINTIFF'S COMPLAINT**

) ***[Jury Demand Endorsed Hereon]***

DANIEL G. JARCHO, ESQ.
c/o Alston & Bird LLP
950 F Street, NW
Washington, DC 20004

and

KATHLEEN BENWAY, ESQ.
c/o Alston & Bird LLP
950 F Street, NW
Washington, DC 20004

Defendants.

Now comes Plaintiff, Mark One Wipes, LLC, and for its Complaint against the above-named Defendants, states and avers:

NATURE OF THE ACTION

1. This is an action for legal malpractice related to deficient legal advice provided to Plaintiff Mark One Wipes, LLC that resulted in over a million dollars in damages. Specifically, Mark One Wipes hired Defendant Alston & Bird LLP (“Alston”) to provide legal advice on how to properly label hand-sanitizing wipes. While the attorneys at Alston who provided legal advice to Mark One Wipes, including, but not limited to, Defendants Kevin S. Minoli, Elise N. Paeffgen, Samuel D. Jockel, Brendan Carroll, Daniel G. Jarcho, and Kathleen Benway, claimed to be well-versed on FDA compliance matters, the advice these attorneys provided for the language to include on the label was fundamentally incorrect, causing U.S. Customs to reject the wipes for import into the United States. As a direct and proximate result of Defendants’ deficient advice, Mark One Wipes had thousands of packets of hand-sanitizing wipes that it could not import into the United States for sale that were improperly labeled and considered a new and unapproved drug by the FDA. This left Mark One Wipes unable to recover its financial

outlays related to the production of the wipes, including, but not limited to, its manufacturing costs, shipping costs, storage costs, and other related costs. In order to fulfill its contracts, Mark One Wipes was required to buy replacement wipes on the market, to the extent it could. The profits on these wipes were a fraction of the profit it would have made had Defendants simply provided accurate advice. Plaintiff seeks compensatory damages, as well as reasonable attorneys' fees and the costs of this litigation.

2. Plaintiff Mark One Wipes asserts a claim under Ohio law for legal malpractice.

JURISDICTION AND VENUE

3. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332. The matter in controversy exceeds Seventy-Five-Thousand Dollars (\$75,000.00), exclusive of interest and costs, and the parties are residents of different states.

4. The Court has personal jurisdiction over Defendants. Defendant Alston is authorized to conduct and do business in Ohio, and its attorneys, including, but not limited to, Defendants Minoli, Paeffgen, Jockel, Carroll, Jarcho, and Benway provided legal advice to Plaintiff, an Ohio limited liability company.

5. Venue in this judicial district is proper pursuant to 28 U.S.C. § 1391(b)(2), as a substantial part of the events giving rise to the claim occurred in this district.

PARTIES

6. Plaintiff Mark One Wipes is, and was at all times relevant, an Ohio limited liability company. Mark One Wipes is owned by Mark One Group, Ltd., an Ohio limited liability company. The owners of Mark One Group, Ltd. are all citizens of Ohio.

7. Defendant Alston & Bird, LLP is a limited liability partnership with its principal place of business in Georgia. In the United States, it has offices in Georgia, Texas, North Carolina, California, New York, and the District of Columbia. Upon information and belief, none of the partners of the firm are citizens of Ohio.

8. Defendant Kevin S. Minoli, Esq., is a partner of Alston and practices in the firm's Washington, D.C. office. Mr. Minoli is a citizen of the District of Columbia.

9. Defendant Elise N. Paeffgen, Esq., is a partner of Alston and practices in the firm's Washington, D.C. office. Ms. Paeffgen is a citizen of the District of Columbia.

10. Defendant Samuel D. Jockel, Esq. is an associate of Alston and practices in the firm's Washington, D.C. office. Mr. Jockel is a citizen of the District of Columbia.

11. Defendant Brendan Carroll, Esq., is a partner of Alston and practices in the firm's Washington, D.C. office. Mr. Carroll is a citizen of the District of Columbia.

12. Defendant Daniel G. Jarcho, Esq., is a partner of Alston and practices in the firm's Washington, D.C. office. Mr. Jarcho is a citizen of Maryland.

13. Defendant Kathleen Benway is a partner of Alston and practices in the firm's Washington, D.C. office. Ms. Benway is a citizen of Virginia.

STATEMENT OF FACTS

14. During the early part of the COVID-19 Pandemic, the United States was dealing with a shortage of personal protective equipment and sanitizing products.

15. In an attempt to help fill this need, Mark One Wipes was formed and headquartered in Ohio. One of Mark One Wipes' goals was to produce and sell hand-sanitizing wipes.

16. Not having manufactured hand-sanitizing wipes previously, Mark One Wipes sought out a law firm with expertise in FDA compliance. To find such a firm, Mark One Wipes reviewed various law firm websites.

17. One such firm website Mark One Wipes found and reviewed was Alston's. The Alston website touted the firm's experience with FDA compliance and enforcement. For instance, Alston's website contained an advisory titled "Food, Drug & Device/FDA/Environment, Land Use & Natural Resources Advisory: Cleaning Up After COVID-19? What You Need to Know *Before* You Manufacture, Import, or Sell Sterilizers, Sanitizers, Purifiers, and Disinfectants."¹ Kevin Minoli, Elise Paeffgen, and Samuel Jockel are three of the authors of the advisory. Minoli and Paeffgen are partners in Alston's D.C. office; Jockel is an associate.

18. Sufficiently impressed by Alston's purported expertise in FDA compliance, Mark One Wipes reached out and spoke with Doug Arnold, a partner in Alston's Atlanta office. Arnold referred Mark One Wipes to Kevin Minoli. Minoli represented to Mark One Wipes that he and his colleagues at Alston were well-versed in compliance matters related to sanitizing products. In fact, Mr. Minoli's biography on the Alston & Bird website claims that he has "Advised companies bringing sanitizer and disinfectant products to market for the first time on compliance with EPA and FDA regulations."²

19. Convinced that Minoli and his colleagues at Alston were experts in product labeling for sanitizing products, Mark One Wipes retained and began working with Minoli, as well as Paeffgen and Jockel in July of 2020.

¹ See <https://www.alston.com/en/insights/publications/2020/04/cleaning-up-after-covid19> (last accessed February 3, 2022).

² See <https://www.alston.com/en/professionals/m/minoli-kevin> (last accessed January 21, 2022).

20. During this process, Minoli and his team conferred with Mark One as to the language that was to be included on the labels. In a July 27, 2020 email that Minoli sent, signing on behalf of Paeffgen, Jockel, and himself, Defendants provided patently incorrect legal advice. In that email, Minoli and his team provided “recommended language that is consistent with FDA regulations or policy” This included the following excerpt:

Drug Facts Panel Content:

- **Uses:** The FDA monograph includes the following indications: “For handwashing to decrease bacteria on the skin.” To stay within that monograph’s authorization, the use listed cannot refer to “allergens” and should instead reflect the FDA language.
- **Directions:** The directions must appear within the Drug Facts panel. The FDA-approved language for the directions section is, “Wet hands thoroughly with product and allow to dry without wiping.” We recommend using the approved language over the option currently on the package or proposed by Justin.

21. Contrary to Minoli’s assertion, this advice was a flagrant misstatement of law. Specifically, Minoli advised Mark One Wipes to use the term “handwashing,” but he was not providing Mark One Wipes advice for a handwashing product. Rather, Mark One Wipes was seeking advice on a hand-sanitizing wipe, which is a handrubbing product. Simply put, he used the wrong word, which had serious consequences for Mark One Wipes, who acted in reliance on that advice.

22. In 2019, the FDA issued a final action that explained the difference between handwashing products and handrubbing products. *See Safety and Effectiveness of Consumer Antiseptic Rubs; Topical Antimicrobial Drug Products for Over-the-Counter Human Use*, 84 FR 14847-01 (Apr. 12, 2019). The FDA final action provided that antiseptic rub products, like hand-sanitizing wipes, are “intended for use without water,” which is distinct from an antiseptic wash product, which requires the use of water. Thus, to say that the wipes was for “handwashing” were to imply that the wipes were to be used with water, which is not how hand-sanitizing wipes work and is not approved by the FDA monograph.

23. Relying on Defendants' advice, Mark One Wipes manufactured hand-sanitizing wipes at its contract factory in Asia and labeled the wipes with the improper language and shipped them to the United States.

24. Upon arrival to U.S. Customs in the fall of 2020, multiple containers of the wipes were flagged for review. Indeed, beginning September 14, 2020, compliance officers at ports of entry in Columbus, Ohio and Los Angeles, California detained ten containers for being improperly labeled.³ Because the labels of the hand-sanitizing wipes stated that the wipes were for "handwashing," compliance officers viewed the products as a new drug that required an approved New Drug Application for import into the United States.

25. In an attempt to resolve the situation, Alston partner Brendan Carroll began the process of attempting to appeal the compliance officers' determination. During the appeals process, Alston partners Daniel Jarcho and Kathleen Benway also provided advice and billed Mark One Wipes for services rendered related to the mis-labeled wipes.

26. In response to Defendants' attempts to correct their blunder, the FDA laid plain the reason for the denial: the wipes' label was incorrect. This was communicated to Mark One Wipes and Defendants on several occasions by the FDA. For example, in a December 7, 2020 email, the FDA's Merrill Racke, Ph.D., explained that the product FDA reviewed and detained, which contained ethyl alcohol, was labeled as a hand washing product, which was improper, because the FDA has not approved ethyl alcohol for hand washing products. Hand sanitizing wipes may contain ethyl alcohol, but the product was not labeled to be a hand sanitizing wipe, because it used the term "handwashing."

³ Five additional containers were flagged for review, but they were later released. Other containers with the same deficient labeling were not reviewed and thus entered the U.S. without the FDA reviewing the label.

27. Defendants realized their mistake and attempted to defend it. In a December 8, 2020 email, Carroll vigorously contended that the product should be treated as a wipe through voluminous responses to the FDA in emails and formal written responses. He argued, for example, that that “wipes are a type of antiseptic rub, not a wash.” (emphasis in original).

28. Defendants’ efforts to overturn the compliance officers’ decision failed. On February 26, 2021, the FDA issued its final refusal. Defendants’ representation of Mark One Wipes related to the hand-sanitizing wipes ended on or shortly after the FDA’s final refusal.

29. Because Customs rejected the ten detained containers, Mark One Wipes then had to transport the wipes out of the country with few options. Carroll instructed Mark One Wipes to relabel the wipes as not for sale and import them back into the United States. Mark One Wipes currently has wipes stored in several warehouses across the United States.

30. In addition to the wipes rejected by Customs, Mark One Wipes also manufactured other wipes that bear the same deficient labeling that was the product of Defendants’ deficient advice and instruction. These wipes are stored in warehouses across the United States.

31. Mark One Wipes is unable to sell or donate the wipes, and thus, the wipes languish in storage incurring additional storage costs each month. Mark One Wipes intends to destroy the wipes but doing so will cost at least \$250,000.

32. Even though it could not import the wipes that it manufactured, Mark One Wipes still had to fill numerous orders for wipes, including to schools, universities, critical

distributors, and medical facilities across the United States. In order to meet these contracts, Mark One Wipes turned to the market itself and bought replacement wipes at a significantly higher cost to fulfill its contracts. Putting aside the cost of the now useless wipes, Mark One Wipes' profit on the replacement wipes was about half of the amount it would have made had Defendants provided competent counsel.

FIRST CLAIM FOR RELIEF
(Legal Malpractice Against all Defendants)

33. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

34. At all times relevant, Defendants Kevin Minoli, Esq., Elise Paeffgen, Esq., Sam Jockel, Esq., Brendan Carroll, Esq., Daniel Jarcho, Esq., and Kathleen Benway, Esq. represented Plaintiff Mark One Wipes, LLC regarding the labeling and import of hand-sanitizing wipes.

35. At all relevant times, an attorney-client relationship existed between Plaintiff Mark One Wipes and Defendants Kevin Minoli, Esq., Elise Paeffgen, Esq., Sam Jockel, Esq., Brendan Carroll, Esq., Daniel Jarcho, Esq., and Kathleen Benway, Esq.

36. While representing Mark One Wipes, Defendants Kevin Minoli, Esq., Elise Paeffgen, Esq., Sam Jockel, Esq., Brendan Carroll, Esq., Daniel Jarcho, Esq., and Kathleen Benway, Esq. owed Mark One Wipes a fiduciary duty and had a duty to zealously and adequately represent Mark One Wipes' interests, provide adequate and appropriate legal counsel, and exercise the degree of knowledge, skill, and care exercised by a reasonably prudent and capable law firm and attorneys under the same or similar circumstances.

37. In the course of their representation of Plaintiff Mark One Wipes, Defendants Kevin Minoli, Esq., Elise Paeffgen, Esq., Sam Jockel, Esq., Brendan Carroll, Esq., Daniel Jarcho, Esq., and Kathleen Benway, Esq. rendered legal representation, advice, counsel, and services which fell below the standard of care which would have been exercised by a reasonably prudent and careful law firm and legal practitioners under the same or similar circumstances, negligently represented Plaintiff's interests, failed to provide appropriate and adequate advice, and otherwise failed to exercise the degree of knowledge, skill, and care reasonably exercised by an attorney under the same or similar circumstances.

38. Among other breaches in the standard of care, Defendants Kevin Minoli, Esq., Elise Paeffgen, Esq., Sam Jockel, Esq., Brendan Carroll, Esq., Daniel Jarcho, Esq., and Kathleen Benway, Esq. negligently advised Plaintiff as to the language to use on the product label for hand-sanitizing wipes.

39. Defendant Alston & Bird LLP is vicariously liable for the malpractice of its attorneys, including, but not limited to, Defendants Kevin Minoli, Esq., Elise Paeffgen, Esq., Sam Jockel, Esq., Brendan Carroll, Esq., Daniel Jarcho, Esq., and Kathleen Benway, Esq., all of whom are either partners or associates of Alston & Bird LLP.

40. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered substantial injury, damage, and loss, including, but not limited, to, the costs of producing a useless product, transportation costs, storage costs, lost profits, current and future business opportunities, and reputational harm.

WHEREFORE, Plaintiff prays for judgment against Defendants for:

- a. Compensatory damages in an amount that will fully and fairly compensate Mark One Wipes for the injury, damage, and

loss, all of which are permanent, that it has suffered and continues to suffer;

- b. Pre- and post-judgment interest;
- c. Attorneys' fees; and
- d. All such other relief to which Plaintiff is entitled and/or the Court deems appropriate.

TRIAL BY JURY ON ALL CLAIMS FOR RELIEF HEREBY DEMANDED.

DATED this 15th day of February 2022

/s/ Stuart E. Scott

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